PTO/SB/08A (08-03)

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Sheet 1

TRADEN INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

of 2

Complete if Known			
Application Number	10/664,803		
Filing Date	September 19, 2003		
First Named Inventor	Unchalee Kositprapa		
Art Unit	1614		
Examiner Name	Not yet assigned		
Attorney Docket Number	141-424		

			U. S. PATEN	TOCUMENTS	
Examiner Initials*	Cite No.1	Document Number Number-Kind Code ^{2 (f known)}	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MF	во	^{US-} 6,099,862	08-08-2000	Chen et al.	
MF	BP	US- 2003/0077297	04-24-2003	Chen et al.	
MF	BQ	us- 2003/0224046	12-04-2003	Rao et al.	
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	FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	
		Country Code ³ Number ⁴ Kind Code ⁵ (# known)	MM-DD-YYYY		Or Relevant Figures Appear	1
MF	CU	WO 99/47125	04-12-2005	Conley et al.		
MF	CV	EP 1 588 708 A1	10-26-2005	Tekeda Pharm. C		
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Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered, Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. Applicant is to place a check mark here if English language

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

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Substitute for form 1449/PTO		Complete If Known			
Outom	10 10 10 10 10 10			Application Number	10/664,803
INF	ORMATION	DIS	CLOSURE	Filing Date	September 19, 2003
STA	STATEMENT BY APPLICANT		First Named Inventor	Unchalee Kositprapa	
	6 1			Art Unit	1614
(Use as many sheets as necessary)		Examiner Name	Not yet assigned		
Sheet	2	of	2	Attorney Docket Number	141-424

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Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
MF	DN	ABDALLA ET AL, Preparation and evaluation of Metaformin Hydrochloride Controlled-Release Tablets, STP Pharma 4(1) pp. 15-20, 1988.	
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Examiner	/Marc Fitzgerald/	Date	11/06/2006
Signature	, ,	Considered	11/00/2000

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 1 of 5

Compl t if Known		
Application Number	10/664,803	
Filing Date	September 19, 2003	
First Named Inventor	Unchalee Kositprapa	
Art Unit		
Examiner Name		
Attorney Docket Number	141-424	

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Examiner Initials		Document Number Number - Kind Code ² (<i>if known</i>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MF	AA	us-3,174,901	03-23-1965	Sterne	
	AB	us-3,960,949	06-01-1976	Ahrens et al.	
	AC		09-04-1979	Fong	
	AD		06-21-1983	Tice et al.	
	AE		08-18-1987	Meguro et al.	·
	AF	us- 4,839,177	06-13-1989	Colombo et al.	
	AG	us- 4,891,223	01-02-1990	Ambegaonkar et al.	
	AH		11-06-1990	Zentner et al.	
	AI	us- 5,294,770	03-15-1994	Riddle et al.	•
	AJ	us- 5,356,913	10-18-1994	Colca	
	AK	us- 5,376,771	12-27-1994	Roy	
	AL	us-5,478,852	12-26-1995	Olefsky et al.	
	AM	us- 5,602,133	02-11-1997	Antonucci et al.	
	AN	us-5,658,474	08-19-1997	Geerke	
	ÃÔ		10-28-1997	Savastano et al.	
	AP	us- 5,698,220	12-16-1997	Cardinal et al.	
	AO.	us-5,719,188	02-17-1998	Colca	
	AŘ	us- 5,859,037	01-12-1999	Whitcomb	
IV	AS	us- 5,916,584	06-29-1999	O'Donoghue et al.	
MF	AT	us- 5,952,356	09-14-1999	Ikeda et al.	

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Examiner Initials	Cite No.1	Foreign Patent Document County Code3 -Number4 - Kind Code4 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	τ ⁴
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Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006

English language Translation is attached.

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1 Applicant's unique citation designation number (optional). 2 See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. 3 Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). 4 For Japanese patent documents, the appropriate symbols as indicated on the Emperor must precede the serial number of the patent document. 5 Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. 8 Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

of 5 Sheet 2

C mplet if Known			
Application Number	10/664,803		
Filing Date	September 19, 2003		
First Named Inventor	Unchalee Kositprapa		
Art Unit			
Examiner Name			
Attorney Docket Number	141-424		

			U.S. PATI	ENT DOCUMENTS	
		Document Number Number-Kind Code ² (if known		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
MF	AU.	∪s- 5,955,106	09-21-1999	Moeckel et al.	•
	<u>AV</u>		01-04-2000	Whitcomb	
	AW	us-6,031,004	02-29-2000	Timmins et al.	
	AX	us-6,099,859	08-08-2000	Cheng et al.	
	AY	us-6,153,632	11-28-2000	Rieveley	
	ΑZ		02-20-2001	Byrd et al.	
	\overline{BA}	us- 6,248,363	06-19-2001 09-18-2001	Patel et al.	• .
	BB	us- 6,291,495		Rieveley	
	BC	us- 6,296,874	10-02-2001 ·	Cutie et al.	
	BD	us- 6,329,403	12-11-2001	Odaka et al.	
	BE	∪s- 6,383,471	05-07-2002	Chen et al.	•
	BF	us-6,403,121	06-11-2002	Adjei et al.	
	BG	us- 2002/0071866	06-13-2002	Geerke	
	BH.	us-6,451,342	09-17-2002	Adjei et al.	
	BI	us-6,475,521	11-05-2002	Timmins et al.	
	BJ	us- 6,524,621	02-25-2003	Adjei et al.	
	BK.	us-2003/0113371	06-19-2003	Dhawan et al.	
	BL		06-26-2003	Seth	
	BM		06-26-2003	Gao et al.	
MF	BN	us. 6,599,284	07-29-2003	Faour	

	FOREIGN PATENT DOCUMENTS									
Examiner Initials	Cite No.1	Foreign Patent Document Country Code ³ -Number ⁴ - Kind Code ⁵ (<i>I known</i>)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Te				
MF	CA	WO 96/09823 '	04-04-1996	Luo et al.						
	СВ	WO 98/11879 ′	03-26-1998	Shell et al.						
	CC	WO 98/55107 /	12-10-1998	Shell et al.						
	CD	WO 99/47128 -	09-23-1999	Timmins et al.						
	CE_	WO 99/55320	11-04-1999	Nishii et al.		Ī				
	CF	WO 00/28989 1	05-25-2000	Lewis et al.						
	CG.	WO 00/72827 ₍	12-07-2000	Straub et al.						
V	CH	WO 01/35940	05-25-2001	Lewis et al.						
	CI	WO 01/35941	05-25-2001	Lilliot et al.	•					
MF	CI	WO 01/82875	11-08-2001	Cutie et al:		<u> </u>				

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English language Translation is attached.

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¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WiPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WiPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.



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INICO	DMATION		COLOCUE	Application Number	10/664,803	
INFORMATION DISCLOSURE				Filing Date	September 19, 2003	
STATEMENT BY APPLICANT				First Named Inventor	Unchalee Kositprapa	
				Art Unit		
(use as many sheets as necessary)			s necessary)	Examiner Name		
Sheet	3	of	5	Attorney Docket Number	141-424	

	U.S. PATENT DOCUMENTS								
Examiner Initials		Document Number Number - Kind Code ² (<i>if known</i>	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear				
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	Cite No.1	Foreign Patent Document County Code3 -Number4 - Kind Code5 (# known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Te
MF	CK		04-11-2002	Gidwani et al.		
	CL	WO 03/004009	01-16-2003	Matharu et al.		
(CM	WO 03/035029	05-01-2003	Louie-Helm et al.		
	CN	WO 03/047529	06-12-2003	Seth et al.		
	CO	EP 0 169 105	01-22-1986	Zentner et al.		
	CP	EP 0 283 369	09-21-1988	Wiernsperger et al.		
	CO	EP 0 381 181	08-08-1995	Wenzel et al.		
	CR	EP 0 749 751	12-27-1996	Ikeda et al.		
_ .	CS	EP 0 753 298	11-21-2001	Tsujita et al.		
MF	CT	EP 0 781 129	07-02-2003	Moeckel et al.		

	Examiner Signature	/Marc Fitzgerald/	Date Considered	11/06/2006
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INFORMATION DISCLOSURE

STATEMENT BY APPLICANT

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Sheet | 4 | of | 5 | | 5 | | 5 | | Compl t if Known

Application Number | 10/664,803

Filing Date | September 19, 2003

First Named Inventor | Unchalce Kositprapa

Group Art Unit | Examiner Name | 141-424

Examiner Initials Cite No.1 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the lem (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, elty and/or country where published			7
MF	DA	P. Karttunen et al., International Journal of Clinical Pharmacology, Therapy and Toxicology, "The pharmacokinetics of metformin: a comparison of the	
		properties of a rapid release and a sustained-release preparation" Vol. 21, No. 1 - 1983, pp. 31-36.	
dissolving		P.J. Pentikainen, International Journal of Clinical Pharmacology, Therapy and Toxicology, "Bioavailability of metformin. Comparison of solution, rapidly dissolving—tablet, and three-sustained-release-products", Vol. 24, No. 4—1986, pp. 213-220.	
	DC	Finnish Monograph of the Diformin®, Retard tablet, with English translation	
Up		O.J. Lucis, MD, Ph.D., MSC, Canada Medical Association J. Pharmacologic Update "The status of metformin in Canada" Vol. 128, January 1, 1983, pgs. 24-26.	
	DE	G. Belcher and D.R. Matthews Experiment and Clinical Endrocrinology & Diabetes, "Safety and tolerability of pioglitazone" Suppl. 2 (2000) pgs. 267-273.	
		Daniel Einhom, MD et al., Clinical Therapeutics "Pioglitazone Hydrochloride in Combination with Metformin in the Treatment of Type 2 Diabetes Mellitus: A Randomized, Placebo-Controlled Study", Vol. 22, No. 12, 2000 pgs. 1395-1413.	
		National Institute for Clinical Excellence Technology Appraisal Guidance - No. 21, "Guidance on the Use of Pioglitazone for Type 2 Diabetes Mellitus" March 2001, pgs. 1-13.	
DH T		The Pharmaceutical Journal, Vol. 265, No. 7122, p. 710 November 11, 2000 Clinical (abstract only).	

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Examiner	/Mana Bibananald/	Date	11/06/2006
Signature	/Marc Fitzgerald/	Considered	

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		-	SOL GOLLDE	Application Number	10/664,803	
INFORMATION DISCLOSURE				Filing Date	September 19, 2003	
STATEMENT BY APPLICANT				First Named Inventor	Unchalee Kositprapa	
				Group Art Unit		
	(use as many she	ets e	s necessary)	Examiner Name		
Sheet	5	of	5	Attorney Docket Number	141-424	

		OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	1
MF DI		Product Labeling for Glucophage® XR (July 2002).	
	DΊ	ADA Professional Section Member Supplement 047 and 0503-506 (Poster) p. A110; A117	
	DK	Website www.findarticles.com, Clinician Reviews, "Insulin-Sensitizing Diabetes Agent" September 1999.	
	DL	ACTOS® product label, Physician's Desk Reference, 55th Edition, pp. 3171-3175	
$\sqrt{}$		Rote Liste No. 11081 the Medicament Mediabet of MEDICE, ChemPharm. Fabrik Pütter GmbH & Co. KG, Kuhloweg 37-39 Iserlohn/Germany, Editio Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	_
MF		Cantor Verlag für Medizin und Naturwissenschaften GmbH, 1993.	
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